K083444

MAR 1 8 2009

510(k) Summary – Tina-Quant C-Reactive Protein Gen. 3

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3723

Contact Person: Kathie J. Goodwin

Date Prepared: November 17th, 2008

Submission Purpose

Roche Diagnostics hereby submits this Special 510(k): Device Modification to provide notification of modifications to our Tina-Quant C-Reactive Protein Gen 3 assay. This assay was most recently cleared for use in K032336 on the Roche/Hitachi Clinical Chemistry analyzers.

Since the K032336 filing, modifications to the CRPL3 assay on the Roche/Hitachi clinical chemistry analyzers include:

- The *Interference section* of the insert was modified regarding potential HAMA interference.
- The lower detection limit was added to the measuring range section in the package insert according to the product specification of <0.2 mg/L.
- Modification to the insert to clarify when calibration is required.

Modifications prompting this filing include:

- The reagent composition for R2 was modified.
- LOB and LOD values were determined and reported in the insert.
- The functional sensitivity was modified.
- The measuring range for the Roche/Hitachi clinical chemistry analyzers was harmonized to 0.3-350 mg/L.
- The Interference with Hemolysis and Lipemia were modified.
- Only standard anticoagulants were tested and claimed; Na-heparin and Na_2 EDTA were not mentioned in the insert.

Submission History	The Tina-Quant C-Reactive Protein assay was originally cleared in K003400. In K032336, the following device modifications were cleared: • Broadening the measuring range of the assay • Increasing the R1 buffer concentration • Deleting citrated plasma and adding K_2-EDTA as acceptable specimen types • Changing the name of the assay to TQ CRP (latex)
Device Name And Classification	Proprietary name: Tina-Quant C-Reactive Protein Gen 3 Common name: CRPL3 Classification name: C-Reactive Protein Immunological Test System Product code: DCN Regulation Citation: 866.5270 Panel: 82 Immunology Class II
Establishment Registration	The establishment registration number for Roche Diagnostics GmbH Penzberg is 9610126.
Device Description	The C-Reactive Protein Gen 3 assay is a particle enhanced turbidimetric assay. Human CRP agglutinates with latex particles coated with monoclonal anti-CRP antibodies. The precipitate is determined turbidimetrically at 570 nm.
Intended use	Immunoturbidometric assay for the in vitro quantitative determination of CRP in human serum and plasma on Roche automated clinical chemistry analyzers.
Substantial equivalence	The Roche Tina-Quant C-Reactive Protein Gen. 3 is substantially equivalent to the Roche Tina-Quant C-Reactive Protein (Latex) (CRPLX) cleared in K032336.

Substantial equivalence – comparison

Feature	Modified Device : Tina-Quant C-Reactive Protein Gen 3	Predicate Device: Tina-Quant C-Reactive Protein (Latex) (K032336)
Intended Use	Immunoturbidimetric assay for the in vitro quantitative determination of CRP in human serum and plasma on *Roche* automated clinical chemistry analyzers.	Immunoturbidimetric assay for the in vitro quantitative determination of CRP in human serum and plasma on automated clinical chemistry analyzers.
Sample Type	Serum Plasma: Li-heparin, K_2-/K_3-EDTA plasma	Serum Plasma: Li-/Na-heparin, Na-/K_3-EDTA, citrate plasma
Instrument Platform	Roche/Hitachi family including H902, H912, H917, Mod P and Mod D. *(See section 4 (Other Supportive Information) for additional information on application to the cobas c501 and c311 clinical chemistry analyzers.)*	Roche/Hitachi family including H902, H911, H912, H917, Mod P and Mod D.
Calibrator	Same	PresiSet Serum Proteins and CFAS Proteins
Calibration frequency	After entering new calibrator values, after reagent lot change and as required following quality control procedures	After reagent lot change and as required following quality control procedures
Controls	Same	CRP T Control N, Precinorm Protein, Precipath Protein
Traceability	Same	Standardized against CRM 470
Reagent Stability	Same	• Up to expiration at 2-8 deg C • R1/R2: 84 days opened and refrigerated on the analyzer

<table>
<tr><td>Measuring Range</td><td>• Roche/Hitachi 901/912/917/Modular P/Modular D analyzers:
0.3-350 mg/L Dilution of samples via the rerun function is a 1:2 dilution.</td><td>• Roche/Hitachi 902:
1-265 mg/L
• Roche/Hitachi 717/Modular D:
1-265 mg/L
1-398 mg/L with rerun
• Roche/Hitachi 904/911/912:
1-260 mg/L
1-520 mg/L with rerun
• Roche/Hitachi 917/Modular P:
1-280 mg/L
1-560 mg/L with rerun</td></tr>
<tr><td>Precision</td><td>Within Run:
<table><tr><th>Sample</th><th>Mean (mg.L)</th><th>SD (mg/L)</th><th>%CV</th></tr><tr><td>Control 1</td><td>3.6</td><td>0.03</td><td>0.85</td></tr><tr><td>Control 2</td><td>42.2</td><td>0.26</td><td>0.61</td></tr><tr><td>H Pool 1</td><td>0.9</td><td>0.03</td><td>4.00</td></tr><tr><td>H Pool 2</td><td>1.6</td><td>0.02</td><td>1.02</td></tr><tr><td>H Pool 3</td><td>18.4</td><td>0.09</td><td>0.48</td></tr></table>Between Run:
<table><tr><th>Sample</th><th>Mean (mg.L)</th><th>SD (mg/L)</th><th>%CV</th></tr><tr><td>Control 1</td><td>3.1</td><td>0.08</td><td>2.7</td></tr><tr><td>Control 2</td><td>41.4</td><td>0.86</td><td>2.1</td></tr><tr><td>H Pool 1</td><td>0.5</td><td>0.03</td><td>6.2</td></tr><tr><td>H Pool 2</td><td>1.5</td><td>0.05</td><td>3.3</td></tr><tr><td>H Pool 3</td><td>39.1</td><td>0.73</td><td>1.9</td></tr></table></td><td>Within Run:
<table><tr><th>Sample</th><th>Mean (mg.L)</th><th>SD (mg/L)</th><th>%CV</th></tr><tr><td>Control 1</td><td>3.36</td><td>0.09</td><td>2.76</td></tr><tr><td>Control 2</td><td>22.17</td><td>0.44</td><td>1.96</td></tr><tr><td>Control 3</td><td>51.12</td><td>0.90</td><td>1.77</td></tr><tr><td>H Pool 1</td><td>5.76</td><td>0.14</td><td>2.50</td></tr><tr><td>H Pool 2</td><td>150.15</td><td>1.14</td><td>0.76</td></tr></table>Between Run:
<table><tr><th>Sample</th><th>Mean (mg.L)</th><th>SD (mg/L)</th><th>%CV</th></tr><tr><td>Control 1</td><td>3.51</td><td>0.16</td><td>4.61</td></tr><tr><td>Control 2</td><td>22.01</td><td>0.62</td><td>2.81</td></tr><tr><td>Control 3</td><td>50.41</td><td>0.94</td><td>1.86</td></tr><tr><td>H Pool 1</td><td>5.99</td><td>0.15</td><td>2.53</td></tr><tr><td>H Pool 2</td><td>146.31</td><td>2.63</td><td>1.80</td></tr></table></td></tr>
<tr><td>Analytical Sensitivity</td><td>Limit of Quantitation (Functional Sensitivity): 0.6 mg/L
LoB: 0.2 mg/L
LoD: 0.3 mg/L</td><td>Functional Sensitivity: 0.88 mg/L</td></tr>
<tr><td>Analytical Specificity</td><td>Not Claimed</td><td>Lower Detection Limit: 0.425 mg/L</td></tr>
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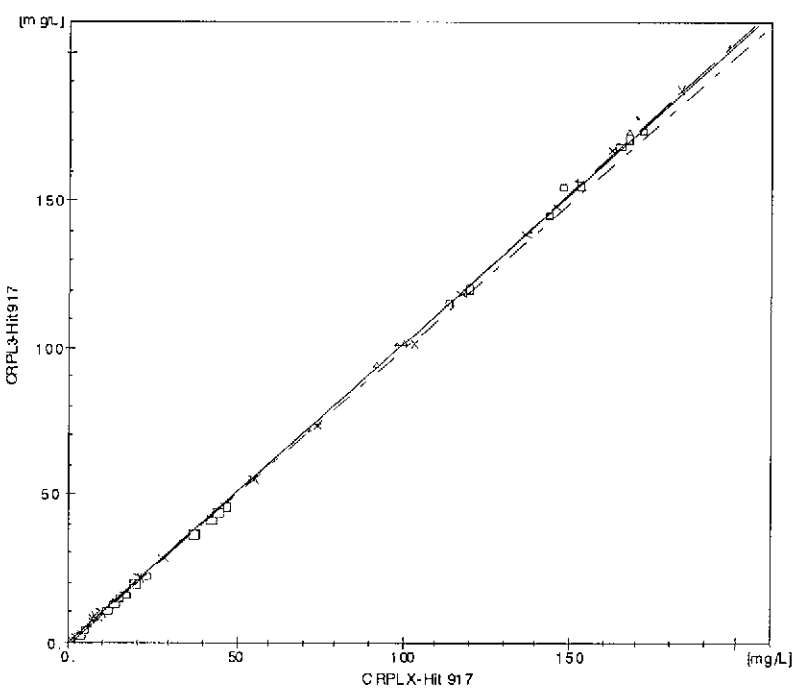
Interferences	**Icterus**: same **Hemolysis:** No significant interference up to1000 mg/dL **Lipemia:** No significant interference up to L index of 1000 **Rheumatoid Factor**: same **High does hook effect**: same	**Icterus**: No significant interference up to 60 mg/dL **Hemolysis:** No significant interference up to 950 mg/dL **Lipemia:** No significant interference up to L index of 1700 **Rheumatoid Factor**: No interference up to 1200 IU/mL **High does hook effect**: No false results up to CRP concentrations of 1200 mg/L
Expected Values	same	<5.0 mg/L
Method Comparison	Tina-Quant C-Reactive Protein Gen 3 on Hitachi 917 compared to Tina-Quant C-Reactive Protein (latex) on Hitachi 917 Slope (Passing Bablok): 1.020 Intercept: 0.000 Coefficients of correlation (r): 1.000  	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 8 2009

Roche Diagnostics Corp.
c/o Ms. Kathie J. Goodwin
Regulatory Affairs Consultant
9115 Hague Rd., P.O. Box 50416
Indianapolis, Indiana 46250-0416

Re: k083444
Trade/Device Name: Tina-Quant C-Reactive Protein (Latex) Gen. 3
Regulation Number: 21 CFR 866.5270
Regulation Name: C- reactive protein immunological test system
Regulatory Class: II
Product Code: DCN
Dated: January 26, 2009
Received: February 2, 2009

Dear Ms. Goodwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240- 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For question regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR), please contact the Division of Surveillance Systems at 240-276-3464. You many obtain other general information on your responsibilities under the Act from the Division of Small Manufactuers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Tina-Quant C-Reactive Protein (Latex) Gen. 3

Indication For Use:

Measurement of c-reactive protein aids in the evaluation of the amount of injury to body tissues.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083444